The German Health Care System and its Impact on Patient Access – Lessons for the U.S.

Since its inception over a decade ago, PIPC has focused on infusing patient-centricity in our health care system. We have been highly focused on patient-centered solutions for evidence-based decision-making, including advocating for the development of high-quality patient reported outcomes data and development of high quality patient-centered comparative clinical effective research, as well as opposing reliance on one-size fits all cost-effectiveness thresholds. Our goal is for high-quality patient-centered data to equip and empower patients and people with disabilities to make decisions, with their providers, about the care and treatment best to address their individual needs.

Proposals to control health care cost growth in the U.S. have frequently involved discussion of the evidenciary standards followed in conducting the comparative clinical effectiveness research and/or value assessments that guide policy decision-making. Many other countries, including England and Canada, rely on assessments of a treatment's cost-effectiveness to set prices. Incorporating use of a one-size fits all metric from another country by attempting to adapt it for use in the U.S. has justly caused concern among stakeholders, particularly patients and persons with disabilities. This is in part because cost effectiveness assessment (CEA) typically relies on an inherently discriminatory metric called the quality-adjusted life year (QALY).[1] The National Council on Disability, an independent federal agency, has advised against the metric's use in public programs, stating that "strict prioritization that is overly reliant on QALYs, similar to the kind utilized in England, is contrary to U.S. civil rights law and disability policy."[2] The concerns raised by NCD are long-held by the disability community and have resulted in policy protections against the use of the QALY, including a statutory prohibition against its use in Medicare.[3]

As public awareness of the QALY's implications for discrimination have grown, U.S. policymakers promoting drug price reform have sought to identify alternatives that rely on comparative clinical effectiveness research (CER) instead of cost-effectiveness. Prominent thought leaders[4], including President Biden,[5] have mentioned that the U.S. could model the German system's coverage and reimbursement policies. The German system does not use QALYs, but it does rely on a one-size fits all method of value assessment to determine coverage and reimbursement.

This shift to increased consideration of CER is reflected in the recently enacted Inflation Reduction Act (IRA), which maintains the prohibition against use of CEA thresholds in Medicare and calls for use of CER in CMS decision-making related to drug prices. Although reliance on CER avoids some of the most egregious flaws of QALY-based cost-effectiveness, the CER approach could be harmful to individual

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[2] https://www.ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[3] 111th Congress of the United States of America. (2010). H.R. 3590 The Patient Protection and Affordable Care Act. *Section 1182*. Washington, DC.
[4] https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/drug-price-moderation-germany-lessons-us-reform-efforts
[5] https://insidehealthpolicy.com/inside-drug-pricing-daily-news/biden-hints-what-could-be-model-drug-pricing-compromise

patients and patient subgroups due to inherent methodological flaws that could favor containing costs over providing high-quality, equitable patient care.

While the German system places far greater reliance on one-size-fits-all CER standards than contemplated in the IRA, it nonetheless holds important lessons for policy-makers in the U.S. It is important to understand how the German system works, including flaws in the German approach to setting drug prices and its impact on patient access to care, including people with disabilities, older adults, and people with chronic conditions; not just those in "good" health. This issue brief examines the use of CER in Germany with a goal of informing a U.S. audience as to how, moving forward, U.S. policymakers can do better by investing in solutions that keep patients at the forefront of our health care decision making.

How does the German health care system work?

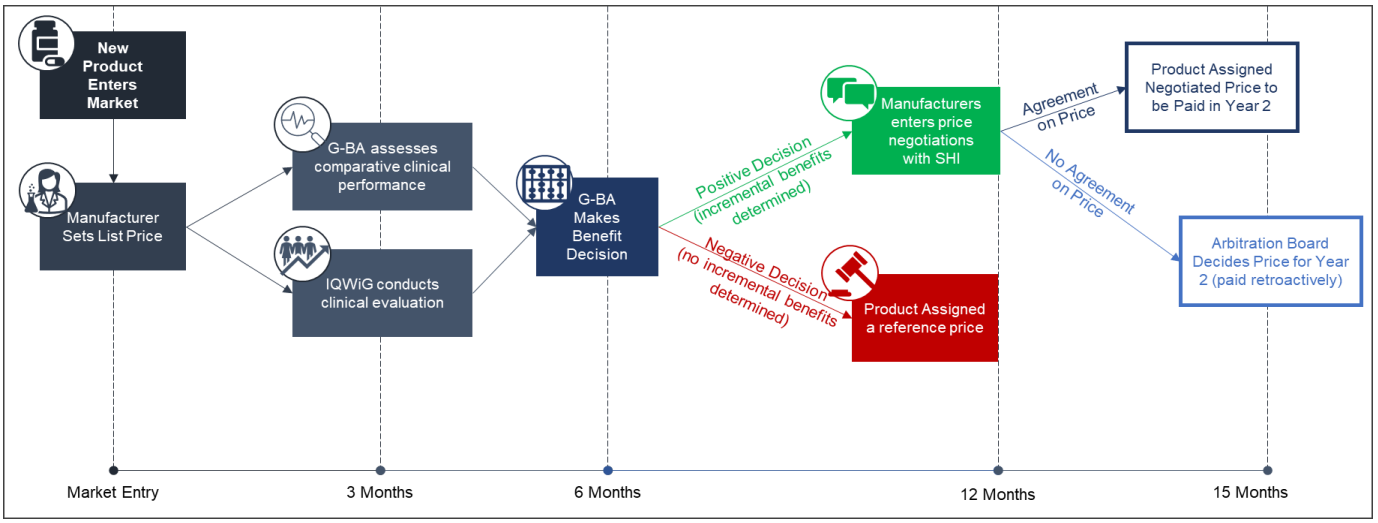
In Germany, the government's assessment of the value of a treatment does not rely on the QALY. Instead, Germany's Joint Federal Committee (G-BA) assesses a treatment's clinical benefits relative to a comparator product that it selects. Even though the G-BA does not rely on the QALY, stakeholders have raised concerns about flaws in how they assess the value of treatments.

In 2011, Germany passed the Pharmaceutical Market Restructuring Act (AMNOG), which created a new paradigm for pharmaceutical coverage and access. Under AMNOG, an umbrella group of public payers determine drug prices through a process whereby treatments are valued based on the G-BA's determination.

The German system allows manufacturers to set their price at launch for 12 months, while the G-BA conducts a value assessment based on rigid requirements for clinical data, allowing the government to choose endpoints and comparators. At the end of the 12-month period, an association representing Germany's public payers (Statutory Health Insurers) sets the price based on the G-BA's value assessment determination. The G-BA is made up of representatives of the national statutory health insurance funds, physicians, and hospital organizations.[6] The G-BA commissions the Institute for Quality and Efficacy in Health Care (IQWiG), an independent institute, to provide recommendations regarding clinical benefit by performing an early benefit assessment. IQWiG bases its assessments on dossiers of information submitted by the manufacturer, the clinical trials used by the European Medicines Agency (EMA), reports by other nations' health technology assessment agencies, and other available evidence.[7] The G-BA determination does not always concur with IQWiG's recommendation.

Following the assessment, manufacturers enter into price negotiations with the Statutory Health Insurance (SHI) system. They have six months to finalize an agreement. If they have not, an arbitration board is called, which must reach a final decision on pricing within three months.[8]

[6] Perleth et al. "A short history of health technology assessment in Germany." International Journal of Technology Assessment in Health Care, 25: Supplement 1. 2009.
[7] https://www.mckinsey.com/industries/life-sciences/our-insights/amnog-revisited
[8] https://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf



Flaws in German HTA System

Although the German system does not rely on QALYs, it has been characterized as both overly rigid and rule oriented,[9] in part due to stringent methods for assessing the value and price of treatments. Its adherence to rigid guidelines for admissible data, poor comparator choices, and failure to meaningfully engage patients has the impact of evaluating the benefit of drugs to the average patient – without accounting for differences among patient needs and preferences within subpopulations – and structuring assessments in ways that do not appropriately represent or account for patient needs. Some of the issues that have been raised by stakeholders include:

- **Germany severely limits the types of evidence that can be considered in assessments.**
- **Germany typically uses an inappropriate comparator, selected based on cost rather than clinical similarity.[10] [11]**
- **Germany restricts the types of endpoints that are acceptable to show the value of treatment, often excluding health outcomes that are important to patients.**
- **The German system does not capture heterogeneity of patient populations.**
- **Patient input does not meaningfully impact the final recommendation.[12]**

Due to these flaws, 60 percent of new medicines have received negative assessments from G-BA, including products that patients view as major treatment advances like CDK4/6 inhibitors and PIK3CA inhibitors for breast cancer.[13] In fact, a recent study found that more innovative treatments were found beneficial by the National Health Institute for Health and Care Excellence (NICE) in England than the G-

[9] https://media.crai.com/wp-content/uploads/2020/09/16163850/CRA-ISPOR-Poster-2019-Discrepancies.pdf
[10] https://media.crai.com/wp-content/uploads/2020/09/16163850/CRA-ISPOR-Poster-2019-Discrepancies.pdf
[11] Ruof et al. "Early benefit assessment (EBA) in Germany: analysing decisions 18 months after introducing the new AMNOG legislation." European Journal of Health Economics. 2014.
[12] https://patientenvertretung.g-ba.de/en
[13] https://www.g-ba.de/downloads/40-1465-7315/2021-02-18_AM-RL-XII_Alpelisib_D-574_TrG_EN.pdf

BA. NICE, which does use QALY-based cost-effectiveness, recommended 78% of technologies appraised during the study period, whereas the G-BA confirmed additional benefit of only 57%.[14]

Below we provide more detail on each of these issues.

Germany often uses an inappropriate comparator, selected based on cost rather than clinical similarity.

The G-BA chooses which comparators to use for a benefit assessment. One recent study found that in many assessments the comparator chosen by G-BA differed from the comparator used in phase III trials, which in some cases led to missing data about the comparator, thereby leading to G-BA finding there to be no additional benefit to the drug in question. In some instances, this has led to manufacturers withdrawing their products from the German market.[15] Half of the drugs evaluated in Germany between 2011 and 2017 did not have comparative evidence against an appropriate comparator (a comparator based on clinical similarity versus cost), which led to no additional benefit being determined by G-BA.[16] While gathering new evidence for an alternative comparator requires the time and cost of new trials and testing, the result of using evidence on inappropriate comparators is that access for German patients is often delayed or blocked when products are temporarily or permanently withdrawn from the German market.

Because the price of the drug is based on its value relative to a comparator, G-BA's choice for a comparator has a considerable impact on the reimbursement price.[17] The G-BA typically uses the least costly available comparator as the price benchmark, even if the treatments have differences that are significant.[18] The most frequent comparator used by G-BA is best supportive care (BSC), the definition of which can vary significantly by indication or therapy area.[19]

Germany severely limits the types of evidence that can be considered in assessments.

In Germany, the methodologies and types of data that can be used in its early benefit assessments are clearly spelled out through regulations. The G-BA strongly prefers Radomized Controlled Trial (RCT) data, in spite of the fact that real world evidence (RWE) can play an important role in regulatory decisions[20] and often can provide a more accurate picture of the effectiveness and value of a treatment for the indicated population.[21] In fact, in the United States, the 21st Century Cures Act, which was designed to accelerate medical innovation, required the Food and Drug Administration (FDA) to publish a framework

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[14] Ramon Schaefer & Michael Schlander (2019) Is the National Institute for Health and Care Excellence (NICE) in England more 'innovation-friendly' than the Federal Joint Committee (G-BA) in Germany?, Expert Review of Pharmacoeconomics & Outcomes Research, 19:4, 453-462, DOI: 10.1080/14737167.2019.1559732

[15] Ruof et al. "Early benefit assessment (EBA) in Germany: analysing decisions 18 months after introducing the new AMNOG legislation." European Journal of Health Economics. 2014.

[16] https://aetion.com/evidence-hub/the-case-for-real-world-evidence-in-germany/

[17] https://www.mckinsey.com/industries/life-sciences/our-insights/amnog-revisited

[18] Ivandik, Victor. "Requirements for benefit assessment in Germany and England-overview and comparison." Health Economics Review. 2014. http://www.healtheconomicsreview.com/content/4/1/12

[19] Ruof et al. "Early benefit assessment (EBA) in Germany: analysing decisions 18 months after introducing the new AMNOG legislation." European Journal of Health Economics. 2014.

[20] https://www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness

[21] https://www.iqvia.com/locations/united-states/blogs/2020/07/real-world-evidence-studies-getting-started

for use of RWE in regulatory decision making. The FDA has done so and widely acknowledges the benefit of using RWE.[22] The G-BA does not accept data sources that are commonly accepted for drug approvals in the U.S. nor data sources considered by other Health Technology Assessment bodies such as NICE in England, viewing evidence from sources other than RCTs with skepticism.[23] The exclusion of RWE leaves little room for the inclusion of patient-reported outcomes data that can be important in determining the value of new treatments to specific patient populations.

Germany restricts the types of endpoints that are acceptable to show the value of treatment, often excluding health outcomes that are important to patients.

Trials based on surrogate endpoints are generally not considered acceptable data. For example, a 2014 report by IQWiG on the validity of surrogate endpoints in oncology found that out of 21 validation studies of breast and colon cancer, overall survival rate was identified as the only valid endpoint and no valid surrogate endpoint was identified.[24] In contrast to this, the FDA in the U.S. has approved several drugs for the same indications based on surrogate endpoints including durable objective overall response rate and progression free survival.[25] The rigidity used in the German model leads to assessments that are not always representative of value to the actual patients in question and may find treatments that do deliver value as providing no additional benefit. For example, IQWiG recommended a "no benefit" rating for the hepatitis C drugs Victrelis (boceprevir) and Incivek (telaprevir), medications that cure 90% of treated hepatitis C patients according to the Centers for Disease Control, on the grounds it did not recognize a sustained virological response as a formally validated patient-relevant endpoint, and therefore saw no proof the drugs offered additional benefits over the comparator therapies interferons and ribavirin.[26] Also, HbA1C is a widely accepted primary endpoint in diabetes trials, but the G-BA has challenged its and use leading to ratings of "no additional benefit" for diabetes drugs.[27]

The German system does not capture heterogeneity of patient populations.

The German system also does not allow for inclusion of robust subgroup analysis. According to IQWiG, subgroup analyses beyond age, sex, disease severity, and country may not yield valid results and are viewed with great caution.[28] Germany's failure to include data on different subgroups leads to most innovative medicines showing "no added benefit, "with innovative medicines for chronic care particularly impacted. This is particularly concerning as chronic illnesses impact communities of color on a greater scale than they do white populations. Studies have shown that "racial and ethnic minorities"

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[22] https://www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness

[23] Ivandik, Victor. "Requirements for benefit assessment in Germany and England-overview and comparison." Health Economics Review. 2014. http://www.healtheconomicsreview.com/content/4/1/12

[24] Ivandik, Victor. "Requirements for benefit assessment in Germany and England-overview and comparison." Health Economics Review. 2014. http://www.healtheconomicsreview.com/content/4/1/12

[25] https://www.fda.gov/drugs/development-resources/table-surrogate-endpoints-were-basis-drug-approval-or-licensure

[26] https://www.mckinsey.com/industries/life-sciences/our-insights/amnog-revisited

[27] Staab et al. "'Market Withdrawals' of medicines in Germany after AMNOG: a comparison of HTA ratings and clinical guideline recommendations." Health Economics Review. 2018. https://doi.org/10.1186/s13561-018-0209-3

[28] Ivandik, Victor. "Requirements for benefit assessment in Germany and England-overview and comparison." Health Economics Review. 2014. http://www.healtheconomicsreview.com/content/4/1/12

are 1.5 to 2 times more likely to have chronic conditions than their white counterparts.[29] One study found that half of new medicines evaluated by IQWiG were found to have no additional benefit while not incorporating data on any subgroup analyses.[30]

This over-reliance on averages is concerning, as we know subgroup analysis of different racial and ethnic groups is essential to ensuring that we move towards an equitable health care system. In the United States, disparities in health care have existed for decades both related to race and ethnicity, as well as location and socio-economic demographics.[31] In reaction to longstanding health inequities, policymakers have recently focused on advancing policies to move toward health equity and eliminating these longstanding injustices.[32,33] To move toward health equity, racial and ethnic subgroups must be considered in value assessments for treatment benefit.[34]

Patients do not have a meaningful seat at the table throughout the process.

German patients have a very narrow role in the assessment of prescription drugs and subsequent negotiation process and therefore have a limited impact on the final recommendations. Patient groups are entitled to participate in discussions and submit evidence to G-BA, but they are not entitled to a decision-making role through a vote in the process.[35] The voting body is comprised of representatives from statutory health insurance funds, hospitals, doctors, psychologists, and dentists.[36] Throughout the EU, there is a recognition that a lack of robust patient engagement throughout the process is a problem. At a conference hosted by the European Commission to discuss upcoming changes in regulation of health technology assessment within the EU, several European-based patient groups stressed the importance of increased patient participation in these assessments.[37]

This stands in contrast to formalized patient participation in the U.S. in the drug approval process at the FDA and the standards for meaningful patient engagement at the Patient-Centered Outcomes Research Institute (PCORI). For example, FDA Advisory Committees include patient representatives. The patient representatives that serve on the Advisory Committees that review drug and biologic therapies have voting privileges.[38] PCORI has an established Patient Engagement Advisory Committee that has led the development of guidance to contracted researchers on patient engagement, compensation of patient partners in research and budgeting for engagement. The legislation creating PCORI includes language

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[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3794652/#:~:text=more%20chronic%20diseases.-,Racial%2Fethnic%20minorities%20are%201.5%20to%202.0%20times%20more%20likely,seem%20to%20be%20getting%20worse.

[30] Ruof et al. "Early benefit assessment (EBA) in Germany: analysing decisions 18 months after introducing the new AMNOG legislation." European Journal of Health Economics. 2014.

[31] https://www.commonwealthfund.org/publications/scorecard/2021/nov/achieving-racial-ethnic-equity-us-health-care-state-performance

[32] https://www.cdc.gov/chronicdisease/healthequity/index.htm

[33] https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities

[34] http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_disparities_whitepaper[2].pdf

[35] https://patientenvertretung.g-ba.de/en

[36] https://www.g-ba.de/downloads/17-98-3769/2018-12-12_G-BA_Infobrosch%C3%BCre_EN_bf.pdf

[37]https://health.ec.europa.eu/health-technology-assessment/regulation-health-technology-assessment_en#:~:text=The%20new%20framework%20covers%20joint,applies%20as%20of%20January%202025.

[38] https://www.fda.gov/patients/about-office-patient-affairs/faqs-about-fda-patient-representative-program

directing the institute to recognize the preferences and outcomes that matter to patients in its studies and to consider the differential impact of treatments and services on subpopulations.

The Impact on Patients and People with Disabilities

The aforementioned flaws in the Germany HTA system have impacted patient access to potentially needed treatments. In a study of products evaluated by the G-BA between 2011 and 2016, 16% of products were withdrawn from the market,[39] and a similar rate of withdrawal has been observed through 2021. The reality that new products may only be temporarily available to patients while the G-BA works through its process factors into provider decision making, causing providers to be hesitant to prescribe an innovative product they believe may ultimately withdraw from the market.[40] This leaves patients caught in the crosshairs of the negotiation process between payers and manufacturers without access to new and needed treatments.

In order to further restrict costs, the G-BA makes a determination of the number of patients and which sub-groups of patients can be treated by a given therapy. The G-BA decisions override physicians' autonomy, which limits providers from making individualized care choices for their patients. This can lead to care decisions being based on budgets, not on what is best for each patient. Physicians have budget ceilings they must abide by, and if they exceed those budgets they can be investigated and penalized. Studies have shown that, because German physicians are incentivized to limit care to keep within budgets, German patients with public insurance often do not receive needed outpatients care at the end of each annual quarter.[41]

Conclusion

It is imperative that we address patient affordability to ensure that Americans have access to the medicines they need. Furthermore, health care systems can achieve this goal while avoiding reliance on discriminatory metrics like the QALY. As illustrated by the experience in Germany, however, simply referencing CER instead of relying on the discriminatory QALY is not a panacea. Often, one-size fits all decisions do not accurately reflect the real value of the treatment in question to all patients. The U.S. has an opportunity to avoid the implications of the rigid requirements that Germany enforces on data sources and comparators that can and cannot be used in value assessment. Different subgroups of patients may respond differently to the same treatment and care plans, making it essential that the evidence reflect those differences and that providers have the flexibility to treat their patients as they determine to be most effective based on their patient's individualized needs.

Experience in Germany offers important lessons for policy-makers at thought leaders in the U.S.:

- As government agencies in the U.S. consider findings from CER studies and assessments, they must take more aggressive steps to build in patient protections and minimize the risks to patients, people with disabilities and minority poplutions from its misuse. This includes agencies

[39] Staab et al. "'Market Withdrawals' of medicines in Germany after AMNOG: a comparison of HTA ratings and clinical guideline recommendations." Health Economics Review. 2018. https://doi.org/10.1186/s13561-018-0209-3
[40] Staab et al. "'Market Withdrawals' of medicines in Germany after AMNOG: a comparison of HTA ratings and clinical guideline recommendations." Health Economics Review. 2018. https://doi.org/10.1186/s13561-018-0209-3
[41] https://www.commonwealthfund.org/publications/newsletter-article/2018/jun/german-physician-reimbursement-system-places-barriers

using existing authority (such as CMS national coverage policy, the Veterans Administration, and state Medicaid agencies) as well as CMS in its implementation of new authority under the Inflation Reduction Act.

- PCORI offers an important reference point for policy-makers by giving patients a seat at the table and vote in decision-making as part of its Board of Governors; meaningfully incorporating principles of patient-centeredness into its methods and processes; recognizing that any single assessment represents only one tool for decision-making, not a rigid rule or formula; and assessing the comparative clinical effectiveness of treatments within the health system as a whole, instead of in budget siloes.
- Rather than applying rigid one-size fits all standards to reimbursement and coverage of treatments and therapies, policy-makers should identify alternative solutions that equip and empower patients and their providers to make well-informed decisions reflecting RWE on the differences among patients and what works for whom.

In conclusion, similar to CEA-based decisions, CER-based government policy could drive health care decisions that fail patients if safeguards are not in place to protect against its misuse. Though the German system does not rely on the QALY, the flawed process by which they determine a treatment's clinical benefits has significant implications for access to care. In some cases, QALY-based systems such as NICE have found more novel treatments to be beneficial than the G-BA. As the U.S. advances increased use of CER in its decisions related to reimbursement and coverage, we encourage meaningful participation from patients and people with disabilities to better understand the limitations of the evidence base, particularly through the lens of health equity. The increased development of patient-reported outcomes and other patient-centered data sources for use in clinical and cost effectiveness will be critical to ensure that patients get the care they want and need.